

## **REMARKS**

### **Non-Finality of Office Action**

The Applicant notes that the body of the Office Action does not include an indication or notice that the Office Action has been made final under MPEP §706.07(a). (See pages 3 and 4). Accordingly, the Applicant has considered the Office Action to be non-final.

### **Claim Rejections – 35 USC §102**

Claims 51-55, 63-68, 70 and 73-85 have been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,928,139 to Koros et al. It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

The entire basis regarding the rejection of the pending claims is set forth in a single paragraph on page 2 of the Office Action. Specifically, the Office Action states that Koros discloses a retractor assembly “having a blade (54), a body (32), and first and second enlarged edges (52) extending in an axial direction forming a channel nested in between (approximately 76/78) to maintain the retractor in a predetermined position relative to the body, or for slidable movement. The channel is open in a lateral direction (not cannulated or closed) and has a concave shaped extending continuously from the first enlarged edge and open in a lateral direction to provide an unobstructed view of the surgical site. The retractor also has first and second supporting members (82) that support a pin (83) that helps to position the blade relatively. The retractor also has a handle portion (34) that sits relative to the other parts of the device. The device also has a distracter tip (60) to facilitate insertion.”

### **Claim Amendments**

The Applicant has rewritten claims 84 and 85 in independent form, and has cancelled independent base claims 79 and 81 without prejudice for possible submission and consideration in a continuing application. Such amendments merely constitute rewriting dependent claims 84 and 85 in independent form, and therefore do not raise any new issues that would require further consideration and/or searching. No other claim amendments have been set forth in this response.

### Rewritten Independent Claims 84 and 85

Rewritten independent claims 84 and 85 each recite, among other elements and features, a retractor body having enlarged edges and defining a channel therebetween, and a retractor blade received within the channel and nested between and engaged with the enlarged edges, and “wherein the retractor blade includes a distractor tip sized and shaped for insertion into an intervertebral space for distraction of the intervertebral space, the distractor tip having a width corresponding to a distracted height of the intervertebral space and a rounded distal end transitioning to the width of the distractor tip to facilitate the insertion into and the distraction of the intervertebral space”, and “wherein the rounded distal end of the distractor tip defines a convex curvature transitioning to the width of the distractor tip”.

As indicated above, page 2 of the Office Action asserts that Koros discloses that “[t]he device also has a distracter tip (60) to facilitate insertion.” The Applicant submits that this general allegation does not set forth sufficient grounds with the requisite specificity to establish a *prima facie* case of anticipation with regard to independent claims 84 and 85. As an initial matter, the distal end of the blade 54 does not comprise “a distractor tip sized and shaped for insertion into an intervertebral space for distraction of the intervertebral space”, and likewise does not have “a width corresponding to a distracted height of the intervertebral space”. Although the Office Action general alleges that “[t]he device also has a distracter tip 60 to facilitate insertion”, the Office Action does not set forth any grounds as to how Koros discloses that the distal end 60 of the blade 54 satisfies the specific elements and features recited in independent claims 84 and 85. Accordingly, a *prima facie* case of anticipation has not been established with regard to either of the rewritten independent claims 84 and 85.

Moreover, as shown in Figure 5 of Koros, the distal end 60 of the blade 54 has a width that is significantly larger than the natural disc 98 and the intervertebral space between the adjacent vertebrae 94, 96, and is therefore clearly not “sized and shaped for insertion into an intervertebral space for distraction of the intervertebral space”, nor does the distal end 60 of the blade 54 have “a width corresponding to a distracted height of the intervertebral space”, as recited in independent claims 84 and 85. Furthermore, the distal end 60 of the blade 54 does not have “a width . . . and a rounded distal end transitioning to the width of the distractor tip to facilitate the insertion into and the distraction of the intervertebral space”, as also recited in

independent claims 84 and 85. As illustrated in Figure 5 of Koros, the distal end 60 of the blade 54 does not constitute a rounded distal end transitioning to the width of the distractor tip that would facilitate insertion into and distraction of the intervertebral space.

Furthermore, rewritten independent claims 84 and 85 each recite that “the rounded distal end of the distractor tip defines a convex curvature transitioning to the width of the distractor tip”. However, as illustrated in Figure 5 of Koros, the distal end 60 of the blade 54 defines a concave curvature extending across the width of the distal end 60, and does not include “a convex curvature” transitioning to the width of a distractor tip, as recited in independent claims 84 and 85. Once more, the Office Action does not set forth any grounds or rational basis as to how Koros discloses that the distal end 60 of the blade 54 includes a rounded distal end defining “a convex curvature transitioning to the width of the distractor tip”. As indicated above, a *prima facie* case of anticipation is not established by the general allegation that “[t]he device also has a distractor tip (60) to facilitate insertion.” Instead, a *prima facie* case of anticipation must be supported by sufficient specificity to set forth reasoned grounds as to how each of the elements and features are disclosed in the cited reference.

For at least these reasons, the Applicant submits that Koros does not disclose each of the elements and features recited in rewritten independent claims 84 and 85. Accordingly, the Applicant respectfully requests withdrawal of the rejection of rewritten independent claims 84 and 85 and allowance of the same.

**Independent Claim 51 and Dependent Claims 52-54, 63-65, 70 and 82**

Independent claim 51 recites, among other elements and features, a retractor body including “first and second enlarged edges . . . defining a channel therebetween” and “at least one supporting member mounted thereon for attaching a retractor pin, and a retractor pin attached to a first one of the at least one supporting member”, and a retractor blade received within the channel defined by the retractor body and nested between and engaged with the first and second enlarged edges to maintain the retractor blade in a predetermined position relative to the retractor body.

As indicated above, it is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element

of the claimed invention must be literally present, arranged as in the claim.” Richardson, 9 USPQ.2d at 1920 (emphasis added). Even assuming arguendo that either of the upper support portions 44, 62 of the Koros device could be construed as a retractor body, and that the outer features 50, 52 and 68, 70 could be construed as “first and second enlarged edges . . . defining a channel therebetween” for receiving the blade portions 54, 64, the upper support portions 44, 62 do not include “at least one supporting member . . . for attaching a retractor pin, and a retractor pin attached to a first one of the at least one supporting member”, as recited in independent claim 51. Instead, it is the blade portion 64 that includes the tubular guides 82 which have been construed as a “supporting member” for receiving the screw 83 (which is the element that has been asserted to constitute “a pin”). This configuration is contrary to the requirements of independent claim 51 which recites that the retractor body includes the “at least one supporting member” and “a retractor pin attached to a first one of the at least one supporting member”. Indeed, the upper support portions 44, 62 of the Koros device do not include any structure that could be construed as a “supporting member” for attachment of the screws 83.

The Applicant further submits that the Koros device is structurally different from and operates in a significantly different manner compared to the apparatus recited in independent claim 51. Specifically, with regard to the Koros device, the blade portions 64 are securely anchored to vertebral bone via the screws 83 extending through the tubular guides 82. (See Figures 1, 3 and 6). However, independent claim 51 recites that the retractor body includes the at least one supporting member, with the retractor pin attached to the supporting member. As should be apparent, the configuration of the Koros device does not satisfy each of the elements and features recited in independent claim 51. Once more, the Office Action does not set forth any grounds or rational basis as to how Koros discloses the above-discussed elements and features recited in independent claim 51.

For at least these reasons, Koros fails to disclose each and every element recited in independent claim 51, and therefore does not anticipate independent claim 51. As a result, a *prima facie* case of anticipation has not been established with regard to independent claim 51. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 51 and allowance of the same.

Claims 52-54, 63-65, 70 and 82 depend either directly or indirectly from independent claim 51 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 51. Additionally, further reasons support the patentability of these claims.

For example, claim 52 recites that “the at least one supporting member defines a hollow tube for receiving the retractor pin”. However, the upper support portions 44, 62 of the Koros device, which are the elements that have been construed as “a retractor body” including at least one supporting member, do not include a hollow tube for receiving the screws 83. Although the blade portion 64 includes tubular guides 82 that could possibly be construed as a hollow tube for receiving the retractor pin, the upper support portions 44, 62 clearly do not define such elements and features.

Additionally, claim 54 recites that “the retractor pin has a handle and a shaft disposed between the pin and the handle and slideably received in the at least one supporting member”. However, the screws 83 of Koros, which are the elements that have been construed as “a pin”, do not include “a handle”. Moreover, the Office Action does not set forth any grounds whatsoever as to how Koros discloses a retractor pin having a handle. Although the Office Action refers to the boss 36 extending from the upper portion 44 of the Koros device as “a handle portion”, the boss 36 is not in any way associated with the screws 83. Accordingly, a *prima facie* case of anticipation has not been established with regard to claim 54.

Furthermore, claim 82 recites that “the retractor pin includes external threads that are threadingly engaged with internal threads defined by the at least one supporting member”. However, the screws 83 of Koros do not include external threads that are threadingly engaged with internal threads defined by the guides 82 of the blade portion 64, which are the features that have been construed as “supporting members”. Additionally, the Office Action does not set forth any grounds whatsoever regarding how the screws 83 define external threads “that are threadingly engaged with internal threads defined by the at least one supporting member”. Indeed, as shown in Figure 5 of Koros, although the distal bone engaging portions of the screws 83 are externally threaded, the threaded bone engaging portions of the screws 83 are not threadingly engaged with any element or structure associated with the retractor 10, but are instead threaded into the adjacent vertebrae 94, 96. Notably, the proximal elongate shank



portions of the screws 83 are smooth and non-threaded so as to freely slide within the tubular guides 82 of the blade portion 64. Accordingly, a *prima facie* case of anticipation has not been established with regard to claim 82.

**Independent Claim 55 and Dependent Claims 66-68**

Independent claim 55 recites, among other elements and features, a retractor body including “first and second enlarged edges . . . defining a channel therebetween” and “a first supporting member and a second supporting member . . . positioned on opposite sides of the channel . . . and adapted for attaching a first and a second retractor pin, respectively” and “the first retractor pin being attached to the first supporting member and the second retractor pin received for movement within the second supporting member”, and a retractor blade received within the channel defined by the retractor body and nested between and engaged with the first and second enlarged edges to maintain the retractor blade in a predetermined position relative to the retractor body.

As indicated above, even assuming *arguendo* that either of the upper support portions 44, 62 of the Koros device could be construed as a retractor body, and that the outer features 50, 52 and 68, 70 could be construed as “first and second enlarged edges . . . defining a channel therebetween” for receiving the blade portions 54, 64, the upper support portions 44, 62 do not include “a first supporting member and a second supporting member . . . positioned on opposite sides of the channel” with a first retractor pin “attached to the first supporting member” and a second retractor pin “received for movement within the second supporting member”, as recited in independent claim 55. Instead, it is the blade portion 64 including the tubular guides 82 which have been construed as “a supporting member” for receiving the screw 83. The upper support portions 44, 62 of the Koros device clearly do not include any structures that could be construed as first and second supporting members positioned on opposite sides of a channel for attachment to the screws 83.

For at least these reasons, Koros fails to disclose each and every element recited in independent claim 55, and therefore does not anticipate independent claim 55. As a result, a *prima facie* case of anticipation has not been established with regard to independent claim 55.

Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 55 and allowance of the same.

Claims 66-68 depend either directly or indirectly from independent claim 55 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 55. Additionally, further reasons support the patentability of these claims. For example, claims 67 and 68 each recite “the first and second supporting members define the first and second enlarged edges of the retractor body engaged with the retractor blade”. However, the tubular guides 82 of the Koros device, which the Office Action has construed as “a supporting member”, does not also define the features 58, which the Office Action has construed as “first and second enlarged edges”.

**Independent Claim 73 and Dependent Claims 74-78, 80 and 83**

Independent claim 73 recites, among other elements and features, a retractor body including “first and second support members defining a channel therebetween and each support member having an enlarged edge extending . . . along the channel” with “a first pin receivable within a first opening in the first support member and a second pin receivable within a second opening in the second support member”, and a retractor blade received within the channel and nested between and engaged with each of the enlarged edges.

As indicated above, even assuming arguendo that either of the upper support portions 44, 62 of the Koros device could be construed as a retractor body defining a channel, and that the outer features 50, 52 and 68, 70 could each be construed as “an enlarged edge extending . . . along the channel” for receiving the blade portions 54, 64, the upper portions 44, 62 of the Koros device do not include “first and second support members” with “a first pin receivable within a first opening in the first support member and a second pin receivable within a second opening in the second support member”, as recited in independent claim 73. Instead, it is the blade portion 64 including the tubular guides 82 which have been construed as “first and second support members” having an opening for receiving the screw 83. Indeed, the upper support portions 44, 62 of the Koros device do not include any structures that could be construed as first and second supporting members defining first and second openings which receive first and second pins.

For at least these reasons, Koros fails to disclose each and every element recited in independent claim 73, and therefore does not anticipate independent claim 73. As a result, a *prima facie* case of anticipation has not been established with regard to independent claim 73. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 73 and allowance of the same.

Claims 74-78, 80 and 83 depend either directly or indirectly from independent claim 73 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 73. Additionally, further reasons support the patentability of these claims.

For example, claim 74 recites that “the second pin includes a handle and a shaft extending therefrom, the shaft comprising the second pin received in the second opening in the second support member”. However, as indicated above with regard to claim 54, the screw 83 of the Koros device, which is the element that has construed as “a pin”, does not include “a handle”. Moreover, the Office Action does not set forth any grounds whatsoever as to how the screws 83 constitute a retractor pin having a handle. Although the Office Action refers to the boss 36 extending from the upper portion 44 of the Koros device as “a handle portion”, the boss 36 is not in any way associated with the screws 83. Accordingly, a *prima facie* case of anticipation has not been established with regard to claim 74.

Additionally, claim 80 recites that “the first and second support members defining the first and second openings that receive the first and second pins also define the first and second enlarged edges of the retractor body”. However, the tubular guides 82 of the Koros device, which the Office Action has construed as “a supporting member” that supports the screw 83, does not also define the features 58, which the Office Action has construed as “first and second enlarged edges”.

Furthermore, claim 83 recites that “one of the first and second pins includes external threads that are threadingly engaged with internal threads defined by a corresponding one of the first and second support members”. However, as indicated above with regard to claim 82, the screws 83 of Koros do not include external threads that are threadingly engaged with internal threads defined by the tubular guides 82 of the blade portion 64, which are the features that have been construed as “supporting members”.



## CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 51-55, 63-68, 70, 73-78, 80 and 82-85.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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